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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,574	02/08/2002	Lone Jeppesen	5698.210-US	2406

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Reza Green, Esq.
Novo Nordisk of North America, Inc.
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,574	JEPPESEN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1, 2, 7, 17, 45-47, and 53-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 2, 7, 17, 46, 47, and 53-55 is/are rejected.

7)☒ Claim(s) 45 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/419,761 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is a divisional application of 09/419,761. The preliminary amendment has been entered. It is noted that the definition of X has been limited to $-(CHR^9)-CH_2-$, -CH=CH-, $-(NR^9)-CH_2-$, $-(CHR^9)-CH_2-CH_2-$, $-CH=(CR^9)-$, $-(CO)-(CHR^9)-$, which is the subject matter of Group I of the restriction presented in 09/419,761.

With claims 3-6, 8-16, 18-44, 48-52, and 56-60 cancelled, the remaining claims 1, 2, 7, 17, 45-47, and 53-55 are considered herein.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **New Matter:** Claims 1, 2, 7, 17, 46, 47 and 53-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitations of *"C_{1-7}-alkyl, C_{2-7}-alkenyl, C_{2-7}-alkynyl, C_{1-7}-alkoxy"*, which has no support in the original disclosure. Although C_{1-7}, or C_{2-7} falls within the range of C_{1-12} disclosed in the specification, there is no preferred

embodiment for selecting a narrower range. Thus, said limitations lack written description as well as enablement.

3. **Lack of Written Description:** Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 53 recites the term "ailments" which has no description as to what diseases would be included.

4. **Utility:** Claim 53 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

A revised utility guidelines require that utilities must be specific, substantial, and credible. By specific, said guidelines call for a particular disorder or disease. In the instant case, the term "ailments" does not point to a particular disease or disorder. By substantial, said guidelines require that utilities must define a "real world" use, and must not constitute further research to identify or reasonably confirm a "real world" context of use. In the instant case, said claim calls for "the treatment of ailments" which is not specific and not substantial as the specification does not appear to list what diseases or disorders are covered by the term "ailments". Furthermore, many diseases included in said term have no known etiology, and/or no treatment such as schizophrenia, Huntington's, cancers, and "common cold", and thus their treatment would require extensive further research. Because applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed. See

Brenner v. Manson, 148 USPQ 689, and **In re Zeigler**, 26 USPQ 2d 1600, 1603 (Fed. Cir. 1996).

Lack of Enablement: Claim 53 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. **Enablement:** Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no reasonable assurance that such a diverse genus of compounds may be useful in treating a plethora of diseases. That is, there is no correlation between the alleged utility and the screening tests. ***In re Fouche***, 169 USPQ 49 (CCPA 1971).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. The term "ailments" does not have a definite metes and bounds. The specification does not list what diseases or disorders would constitute "ailments". Said term covers many disorders that may not be related to Peroxisome Proliferator-Activated Receptors such as "common cold", asthma, arthritis, osteoporosis, schizophrenia, lupus, cerebral palsy, etc. Thus, it is unclear what disorders are intended.

b. Claim 54 recites the limitation of *"conditions mediated by nuclear receptors, in particular the Peroxisome Proliferator-Activated Receptors (PPAR),"* which is unclear for two reasons. First, "conditions mediated by" is not clear as to what is meant by the term "mediated". Would said term mean 'activated'? 'deactivated'? or 'inhibited'? It is not clear what biological pathway is intended (i.e., agonizing, or antagonizing). Second, the phrase "in particular" renders the claim indefinite because it is not clear if only PPAR is affected, or other nuclear receptors are also affected. In essence, the phrase "in particular" presents the situation of "broad limitation followed by narrow limitation" see ***Ex parte Wu***, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989). The Board stated that "broad limitation followed by narrow limitation" can render a claim indefinite by raising a question or doubt as to whether the limitation introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of ***Ex parte Steigewald***, 131 USPQ 74 (Bd. App. 1961); ***Ex parte Hall***, 83 USPQ 38 (Bd. App. 1948); and ***Ex parte Hasche***, 86 USPQ 481 (Bd. App. 1949).

Claim Objections

7. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A search in the pertinent art does not yield any reference teaching or suggesting the claimed species.

References cited on PTO-892

8. The references listed on PTO-892 present the state of the art. While they teach the tricyclic system having azepin, diazepin, or eight-membered nitrogen containing ring, they fail to teach a substituent corresponding to the claimed variable "A".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (5:00-12:30) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong
***
September 4, 2003

Alan L. Rotman
ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED COMPLIANCE IS MANDATORY - Effective Date: July 30, 2003

All amendments filed on or after the effective date noted above must comply with revised 37 CFR 1.121. See Final Rule: **Changes To Implement Electronic Maintenance of Official Patent Application Records** (68 *Fed. Reg.* 38611 (June 30, 2003), posted on the Office's website at: http://www.uspto.gov/web/patents/ifw/ with related information. The amendment practice set forth in revised 37 CFR 1.121, and described below, replaces the voluntary revised amendment format available to applicants since February 2003. **NOTE: STRICT COMPLIANCE WITH THE REVISED 37 CFR 1.121 IS REQUIRED AS OF THE EFFECTIVE DATE (July 30, 2003).** The Office will notify applicants of amendments that are not accepted because they do not comply with revised 37 CFR 1.121 via a Notice of Non-Compliant Amendment. See MPEP 714.03 (Rev. 1, Feb. 2003). The non-compliant section(s) will have to be corrected and the entire corrected section(s) resubmitted within a set period.

Bold underlined italic font has been used below to highlight the major differences between the revised 37 CFR 1.121 and the voluntary revised amendment format that applicants could use since February, 2003.
Note: The amendment practice for **reissues** and **reexamination proceedings**, except for drawings, has not changed.

REVISED AMENDMENT PRACTICE

I. Begin each section of an amendment document on a separate sheet:
Each section of an amendment document (*e.g.*, Specification Amendments, Claim Amendments, Drawing Amendments, and Remarks) must begin on a separate sheet. Starting each separate section on a new page will facilitate the process of separately indexing and scanning each section of an amendment document for placement in an image file wrapper.

II. Two versions of amended part(s) no longer required:
37 CFR 1.121 has been revised to no longer require two versions (a clean version and a marked up version) of each replacement paragraph or section, or amended claim. Note, however, the requirements for a clean version and a marked up version for substitute specifications under 37 CFR 1.125 have been retained.

A) **Amendments to the claims:**
Each amendment document that includes a change to an existing claim, cancellation of a claim or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number in the listing, the status must be indicated in a parenthetical expression, and **the text of each pending claim** (with markings to show current changes) must be presented. The claims in the listing will replace all prior claims in the application.

(1) The current status of all of the claims in the application, including any previously canceled, not entered or withdrawn claims, must be given in a parenthetical expression following the claim number using only one of the following seven status identifiers: (original), (currently amended), (canceled), (withdrawn), (new), ***(previously presented) and (not entered).*** The text of all pending claims, ***including withdrawn claims,*** must be submitted each time any claim is amended. Canceled ***and not entered*** claims must be indicated by only the claim number and status, without presenting the text of the claims.

(2) The text of all claims being currently amended must be presented in the claim listing with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for ***deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change*** (e.g., ~~number 4 as~~ ***number 14 as***). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended," and "withdrawn" that are being amended, may include markings.

(3) The text of pending claims not being currently amended, ***including withdrawn claims,*** must be presented in the claim listing in clean version, *i.e.*, without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version except to omit markings that may have been present in the immediate prior version of the claims.

(4) A claim being canceled must be listed in the claim listing with the status identifier "canceled"; the text of the claim must not be presented. Providing an instruction to cancel is optional.
(5) Any claims added by amendment must be presented in the claim listing with the status identifier "(new)"; the text of the claim must not be underlined
(6) All of the claims in the claim listing must be presented in ascending numerical order. Consecutive canceled, or not entered, claims may be aggregated into one statement (*e.g.*, Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (previously presented): A bucket with a handle.

Claim 7 (withdrawn): A handle comprising an elongated wire.

Claim 8 (withdrawn): The handle of claim 7 further comprising a plastic grip.

Claim 9 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 10 (original): The bucket of claim 9 wherein the handle is made of wood.

Claim 11 (canceled)

Claim 12 (not entered)

Claim 13 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:
Amendments to the specification, including the abstract, must be made by presenting a replacement paragraph or section or abstract marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. Newly added paragraphs or sections, including a new abstract (instead of a replacement abstract), must not be underlined. A replacement or new abstract must be submitted on a separate sheet, 37 CFR 1.72. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per 37 CFR 1.125.

The changes in any replacement paragraph or section, or substitute specification must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for *deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change* (*e.g.*, ~~*number 1 as*~~ *number 14 as)*

C) Amendments to drawing figures:
Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment, *and may be accompanied by a marked-up copy of one or more of the figures being amended, with annotations.* Any replacement drawing sheet must *be identified in the top margin as "Replacement Sheet"* and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. *Any marked-up (annotated) copy showing changes must be labeled "Annotated Marked-up Drawings" and accompany the replacement sheet in the amendment (e.g., as an appendix).* The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to: Elizabeth Dougherty or Gena Jones, Legal Advisors, or Joe Narcavage, Senior Special Projects Examiner, Office of Patent Legal Administration, by e-mail to patentpractice@uspto.gov or by phone at (703) 305-1616.